

highlight specific reference characters. Revised formal drawings for FIGS. 1-16 including the changes indicated on the marked-up copies of FIGS. 5, 7, and 14 are submitted herewith.

**In the Specification**

Please amend the specification as follows. A marked-up copy of the amendments to the specification is attached to this response.

On page 6, please delete the paragraph beginning on line 24 and ending on page 7, line 10, and substitute the following therefor:

C1

A sensor monitoring system 19, including an exhalation flowmeter 11 a circuit resistance sensor 9 and a pressure sensor 7 in communication with the flexible airway tubing 21, provide signals to a embedded controller 14 relating to airway pressure, flow and resistance. These measured values are stored in a database 13. These values are also compared with values preselected by a user by way of the embedded controller 14 to calculate the amount of negative pressure to be generated in the ventilator 17 in order to produce an airway pressure greater than zero and less than positive end-expiratory pressure. A pneumatic system 41 regulates the flow of gas delivered from the source of pressurized gas 45 through a Venturi valve within the ventilator 17 to produce this negative pressure. One embodiment of such a pneumatic system 41 is described in U.S. patent number 5,664,563, owned by the assignee of the present invention, incorporated herein by reference. A pressure sensor 51 measures the amount of negative pressure produced within the ventilator 17 and transmits these data to the embedded controller 14. These data are stored in the database 13 and displayed on the display 24 of the display controller 12.

On page 7, please delete the paragraph beginning on line 11 and ending on line 22, and substitute the following therefor:

C2

Initially, the clinician 16 enters target values into the system 10 by way of the input device 26 of the display controller 12. Each of these target values is compared with a corresponding current value of ventilatory unit pressure, airway pressure, airway flow and airway resistance by the embedded controller 14. Upon determining that there is a difference between current pressure, flow and resistance values and those values entered by the clinician 16, the embedded controller 14 generates a signal to the pneumatic system 41 so that the pneumatic system 41 changes the amount of negative pressure produced by the ventilator 17. The ventilator 17 is in pneumatic communication with a flexible airway tubing 21 capable of attachment to a patient 20. The clinician 16 can also directly adjust the pneumatic system 41 by manipulating a plurality of controls on the input device 26 of the display controller 12.

On page 7, please delete the paragraph beginning on line 23 and ending on line 29, and substitute the following therefor:

C3

The clinician 16 enters numerical data at the display controller 12 relating to the desired level of airway resistance in the flexible airway tubing 21 or relating to the desired amount of negative pressure in the pneumatic system 41. These entered values signal the pneumatic system 41 to change the amount of negative pressure on a per breath basis within the pneumatic system 41 until the pressure in the pneumatic system 41 or the resistance in the flexible airway tubing 21 equals the value entered by the clinician 16.

On page 10, please delete the paragraph beginning on line 20 and ending on page 11, line 2, and substitute the following therefor:

C4

In more detail, and referring also to FIG. 4, a block diagram of the ventilator 17 in communication with the flexible airway tubing 21 that is the conduit for inhalation from the patient 20 is depicted. The pneumatic system 41 regulates the amount of negative pressure produced within a rigid chamber 43 by adjusting the flow of gas from a source of pressurized gas 45 through a Venturi valve 47. Within the rigid chamber 43 is a flexible canister 49. Negative pressure produced within the rigid chamber 43 is transmitted to the flexible canister 49 and thus to the patient flexible airway tubing 21 which is in pneumatic communication with the flexible canister 49. In this way, negative pressure is applied to the patient flexible airway tubing 21 to assist the patient's exhalation through the canister 49 into the medical ventilator 17. Pressure within the flexible canister 49 is measured by a pressure sensor 51. These data are transmitted to the embedded controller 14.

On page 11, please delete the paragraph beginning on line 3 and ending on line 25, and substitute the following therefor:

C5

Now referring also to FIG. 5 a detailed functional block diagram of the ventilator control system 10 is depicted. As shown, the clinician 16 manipulates a control setting slider 34 to change or set one or more breath parameters. A change alert panel 36 informs the clinician 16 of the process, from input to implementation, to assure him that his input information is being processed properly. As noted previously, a change to one or more breath parameters will lead to changes in one or more data structures of the therapy control structure hierarchy. It is noted that FIG. 5 provides an example of a breath parameter change which results in a change at the level of the breath control structure. The validation process

C5

includes the processor 22 validating 38 the clinician's inputs and creating 40 a breath control structure which is stored in memory. The display controller 12 transmits the breath control structure to the embedded controller 14 and informs the clinician 16 of successful transmission via the change alert panel 36. The embedded controller 14 initially stores 44 the breath control structure in local memory. The embedded controller 14 re-validates 46 the settings within the breath control structure. The embedded controller 14 implements 48 the validated breath control structure 48 using a breath control algorithm 50 and provides signals to the pneumatic system 41 for simultaneously changing one or more control settings at the appropriate time. This process enables the user to change or implement a new therapy so that the therapy delivered to the patient is essentially uninterrupted, and the new therapy is synchronized with the next inspiration. If, however, any step in the process is not completed, the clinician is alerted via the panel 36 to the cause of the error and the process is terminated.

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On page 11, please delete the paragraph beginning on line 26 and ending on page 12, line 8, and substitute the following therefore:

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C6

The ventilator control system 10 provides two independent feedback paths to assure the clinician 16 that his setting change has been properly implemented. First, the embedded controller 14 calculates a series of breath monitoring values and sends them to the display controller 12, where the values are displayed 60 contiguous to the desired setting controls. The breath monitoring values can be, for example, set breath rate, measured breath rate, set tidal volume, measured inhaled volume, and measured exhaled volume. The display controller 12 also displays 60 a series of measurements (e.g., peak airway pressure, peak airway flow, and PEEP) from the waveform data both numerically and graphically. Second,

C6  
the display controller 12 displays 54 the continuous waveforms on the display 24 (shown in FIG. 2). The waveforms are derived 56 from raw data from the sensors 19, returned from the embedded controller 14 and passed directly to the display 24 (shown in FIG. 2).

On page 13, please delete the paragraph beginning on line 6 and ending on line 12, and substitute the following therefor:

C7  
As the patient exhales, the system 10 monitors both the patient airway flow and the patient airway pressure. Referring to FIG. 6, if the gas flow is seen to flow into the patient, and the pressure slope is positive, the flow into the patient is considered to be a result of overshoot and no inhalation is triggered (FIG. 6a). If the pressure decreases and the gas flow is into the patient (Step 300), then the total amount of gas inhaled by the patient is measured, and compared to the trigger volume (Step 310).

On page 13, please delete the paragraph beginning on line 13 and ending on line 17, and substitute the following therefore:

C8  
If the total amount of gas inhaled is greater than the trigger volume and this value has been reached in less than 200 msec, a breath is initiated. If the trigger volume has not been reached and it is taking more than 200 msec, the volume of inhaled gas is continued to be measured until the trigger volume has been reached (Steps 320, 330).

On page 18, please delete the paragraph beginning on line 1 and ending on line 13, and substitute the following therefore:

C9  
By selecting one of the control buttons on the touch display, the clinician 16 can display the control slider 104 for the control setting in a

C9

fixed location at the right of the screen, as shown in FIG. 9. A scroll bar title 106, located near the top of the slider 104, indicates the name of the control setting. The full vertical range 108 indicates the allowed set limits. The center slider indicates the current position 110 and the range 112 of the control setting. The upper and lower sliders (114, 116) indicate the current alarm limit settings. The position 110 of the current setting within the allowable range 112 and within the alarm limits (114, 116) is readily apparent to the clinician. The clinician can move any of the sliders to change the set values in steps of approximately 1% of the allowable range, or with the "Exact" button selected, approximately ten times more precision (i.e., about 0.1% of the allowable range). When the desired value is reached, the clinician depresses the Accept Changes button to change the parameter.

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On page 21, please delete the paragraph beginning on page 1 and ending on page 17, and substitute the following therefore:

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C10

Referring again to FIG. 9, the display controller includes software for manipulating the characteristics of the breath parameter Airway Pressure 106 displayed in the control slider 104 on the touch-sensitive display 24. When the clinician 16 selects a control button to display the control slider 104 for Airway Pressure, the display controller 12 dynamically defines a touch zone on the touch-sensitive display. More specifically, touch zones are defined for each slider (i.e., high alarm, low alarm, position and allowable range) within the control slider. Each touch zone is slightly larger than the displayed slider. By way of example only, the touch zone for high alarm may extend into regions 118 to either side of the color coded high alarm region 114. The display controller 12 receives a touch signal when the clinician 16 touches any location within the touch zone and changes the range of the high alarm slider breath parameter in

C10  
response to the touch signal. In other words, the display controller 12 increases the high alarm limit in response to the clinician 16 touching a location within the region 118 and dragging his finger in an upward path. Because his finger does not obscure the high alarm limit, the clinician can actually see the limit being change as it happens.

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On page 31, please delete the paragraph beginning on line 1 and ending on line 11, and substitute the following therefore:

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C11  
The database 13 is electrically coupled to the display controller processor 22 and stores a plurality of patient protocols. Each patient protocol includes at least a set of breath parameters and patient data. The breath parameter may be organized as one or more therapy control structures. The clinician 16 selects a patient protocol by depressing a touch zone on the display 24. The processor 22 copies the selected patient protocol into memory. In the operational mode, the processor 22 instructs the embedded controller 14 to simultaneously adjust the controls of the pneumatic system 18 using the selected patient protocol. In the simulation mode, the simulator 212 simulates the adjustment to the ventilator pneumatic system 41 and the resulting response of the patient's pulmonary system.

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### **In the Claims**

Please amend claims 13, 15, 18, 20, 21, 23, 24, 25, 29, 31, 32, 33, and 38 as follows. A marked-up copy of the amendments to the claims is attached to this response.

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C12  
13. (Amended) The ventilator control system of claim 11 further comprising a display in communication with said controller for displaying a user interface comprising software-generated images representing status of a patient's pulmonary system and a set of breath parameters.

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